C3

PHASE 3 SUMMARY OF MRID 00093998:

ACUTE ORAL TOXICITY IN THE RAT

STUDY # 6818A

FLUMETRALIN

GUIDELINE REFERENCE:

81-1 ACUTE ORAL TOXICITY IN THE RAT

SUMMARY PREPARED BY:

JACQUELINE GILLIS, Ph.D.

MERRILL TISDEL

14 SEPTEMBER 1990

ORIGINAL STUDY PREPARED BY:

FOOD AND DRUG RESEARCH LABORATORIES, INC.

WAVERLY, NEW YORK

C3

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company: CIBA-GEIGY Corporation (Typed Name)

Company Agent: Thomas Parshley (Typed Name)

Title: Senior Reg. Specialist

Signature: _____ Date: _____

These data are the property of the Agricultural Division of CIBA-GEIGY Corporation, and as such, are considered to be confidential for all purposes other than compliance with FIFRA §10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality which may exist under any other statute or in any other country.

FDRL Study No. 6818A

Acute Oral Toxicity Study in Rats
of CGA-41065 Technical

GLP Compliance Statement

I hereby certify that this study was performed in compliance with regulations for Good Laboratory Practice (GLP) as described by FDA (21 CFR Part 58) and although completed and reported prior to promulgation of the EPA GLP, essentially in compliance with EPA (40 CFR Part 160).

Elizabeth Laga
Study Director

9/5/90
Date

This study does not meet the requirements for 40 CFR Part 160 since it was conducted prior to the issuance of the EPA Good Laboratory Practice Standards. It was conducted according to the FDA Good Laboratory Practice Standards as indicated above.

Submitter/Sponsor of Study: Merrill Tisdel

Merrill Tisdel
Agricultural Division
CIBA-GEIGY Corporation
Greensboro, North Carolina

Certification of Availability of Raw Data

I hereby certify that the submitter possesses or has access to the raw data used in or generated by the study summarized in this document.

Submitter's Representative:

Signature/Date: Merrill Tisdel 10.15.90

Typed Name: Merrill Tisdel

Title: Toxicologist

Certification of Accuracy of Summary and Adequacy of the Study

I certify, in compliance with FIFRA section 4(e)(1)(A), that this summary accurately represents the data presented in the report(s) of this study cited by MRID, and that this study fully satisfies all pertinent requirements of the OPP Guideline it addresses.

Submitter's Representative:

Signature/Date: Merrill Tisdel 10.15.90

Typed Name: Merrill Tisdel

Title: Toxicologist

R406MT0628MG

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. Y — Technical form of the active ingredient tested. (for reregistration only)
2.* Y — At least 5 young adult rats/sex/group
3. Y — Dosing, single oral may be administered over 24 hrs.
4.* Y — Vehicle control if other than water.
5. Y — Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6. Y — Individual observations at least once a day.
7. Y — Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8. Y — Individual daily observations.
9.* Y — Individual body weights.
10.* Y — Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

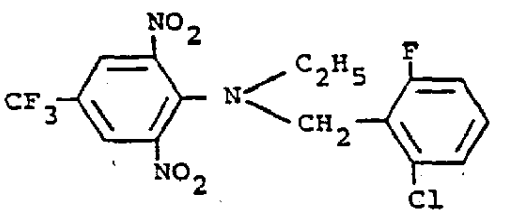
C3

IDENTIFICATION OF TEST MATERIAL

Chemical Name

CAS Name:	N-(2-Chloro-6-fluorobenzyl)-N-ethyl-α,α,α,-trifluoro-2,6-dinitro-p-toluidine or 2-Chloro-N-[2,6-dinitro-4-(trifluoromethyl)phenyl]-N-ethyl-6-fluorobenzenemethanamine
Common Name:	Flumetralin
Trade Name:	Prime +®
CIBA-GEIGY Code Number:	CGA-41065
CAS Registry Number:	62924-70-3
EPA Shaughnessy Number:	Unknown

Chemical Structure:



Percent Active Ingredient

92% minimum

Flumetralin: 81-1: Acute Oral Toxicity in the Rat

1. The test article was Flumetralin (CGA-41065) Technical, a bright orange crystalline substance, FL-810009, purity 96.4%.

2. Five male and five female Sprague-Dawley rats were treated at one dose level (a limit dose). A concurrent control group of five male and five female rats was treated with the vehicle alone.

3. The dose was administered as a single dose by oral intubation.

4. The vehicle used was corn oil (50% w/v).

5. Doses tested and results were:

Dose (mg/kg)	Number Dead/Number Treated		
	Males	Females	Overall
5000 - Vehicle Control	0/5	0/5	0/10
5000 - Test Article	0/5	0/5	0/10
Test Article LD_{50} (mg/kg)	>5000	>5000	>5000

6. Observations for pharmacologic and/or toxicologic effects and mortality were recorded approximately 2.5 hours after dosing. Observations on the day of dosing in the test animals were moderate diarrhea in three males and a dried bloody nose in one male. Three males in the vehicle control group had moderate diarrhea.

7. Individual observations were made twice daily for 14 days following dosing. Bright yellow urine was observed in all test animals for two to four days following dosing. There were no other treatment-related observations for either the vehicle control or test animals during the 14 days following dosing.

8. See Items 6 and 7.

9.

	Body Weights (g) (Mean/Number Alive)					
	Males			Females		
Group	Initial	Day 7	Day 14	Initial	Day 7	Day 14
Vehicle Control	168/5	229/5	270/5	183/5	216/5	224/5
Test Article	176/5	227/5	273/5	174/5	208/5	218/5

10. A gross necropsy examination was conducted on each control and test group animal at the termination of the study. No treatment-related abnormalities were observed.

11. There were no changes from the Acceptance Criteria in this study.

GILLIS:R501SW0921JG/MT